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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>		Application Number	10/757,077
		Filing Date	January 14, 2004
		First Named Inventor	Lance E. Steward
		Art Unit	Not Yet Assigned
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	12	Attorney Docket Number	ALLE0014-103 (17355CIP3)

ENCLOSURES (check all that apply)				
<input type="checkbox"/> Fee Transmittal Form  <input type="checkbox"/> Fee Attached  <input type="checkbox"/> Amendment / Reply  <input type="checkbox"/> After Final  <input type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input checked="" type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Response to Missing Parts/ Incomplete Application  <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s)  <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition  <input type="checkbox"/> Petition to Convert to a Provisional Application  <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences  <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):  References CX, CY, CZ, DA and DB.		
<table border="1"><tr><td>Remarks</td><td></td></tr></table>			Remarks	
Remarks				

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	David A. Sadewasser/Reg. No. 55,587
Signature	<i>David A. Sadewasser</i>
Date	<i>April 26, 2004</i>

CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Typed or printed name	David A. Sadewasser		
Signature	<i>David A. Sadewasser</i>	Date	<i>April 26, 2004</i>

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



ALLE0014-103 (17355CIP3)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of: Lance E. Steward, et al.

Serial No.: 10/757,077

Group Art Unit: Not Yet Assigned

Filing Date: January 14, 2004

Examiner: Not Yet Assigned

For: CLOSTRIDIAL NEUROTOXIN  
COMPOSITIONS AND MODIFIED  
CLOSTRIDIAL NEUROTOXINS

DATE OF DEPOSIT: April 26, 2004  
I HEREBY CERTIFY THAT THIS PAPER IS BEING  
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ALEXANDRIA, VA 22313-1450

David A. Sadewasser

TYPED NAME: David A. Sadewasser  
REGISTRATION NO: 55,587

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

**This Information Disclosure Statement is being filed:**

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before** the mailing date of a first Office Action on the merits.
- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
- ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), a Petition requesting consideration of the Information Disclosure Statement and the Petition Fee of \$130.00 set forth in 37 C.F.R. § 1.17(i)(1) (see "Statement," "Petition," and "Fees" below).
- ☒ Copies of references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are enclosed.

**EXCEPT THAT:**

- ☐ In view of the voluminous nature of reference @@, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.

☒ Copies of references (AU-CW) listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and Trademark Office in parent application Serial No. 10/163,106, filed on June 4, 2002 and Serial No. 09/910,346, filed on July 20, 2001. References (AA-AT) are newly cited United States patents and are not required to be submitted.

☒ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

**Statement under 37 C.F.R. § 1.97(e)**

☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$\_\_\_\_\_. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$\_\_\_\_\_. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.

☒ No fee or Statement is required under 37 C.F.R. § 1.97(b).

Respectfully submitted,

*David A. Sadewasser*

David A. Sadewasser  
Registration No. 55,587

Dated: April 26, 2004

COZEN O'CONNOR, P.C.  
1900 Market Street, 5<sup>th</sup> Floor  
Philadelphia, PA 19103-3508  
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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 7

**Complete if Known**

Application Number	10/757,077
Filing Date	January 14, 2004
First Named Inventor	Lance E. Steward
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	ALLE0014-103 (17335CIP3)

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	AA	US-6,458,365	10/01/2002	Aoki, et al	
	AB	US- 5,766,605	06/16/1998	Sanders et al	
	AC	US- 5,714,468	02/03/1998	Dao	
	AD	US- 6,464,986	10/15/2002	Aoki et al	
	AE	US- 6,113,915	09/05/2000	Aoki et al	
	AF	US- 6,306,403	10/23/2001	Donovan	
	AG	US- 6,299,893	10/09/2001	Schwartz et al	
	AH	US- 5,670,484	09/23/1997	Binder	
	AI	US- 6,423,319	07/23/2002	Brooks et al	
	AJ	US- 6,139,845	10/31/2000	Donovan	
	AK	US- 6,143,306	11/07/2000	Donovan	
	AL	US- 5,437,291	08/01/1995	Pasricha et al	
	AM	US- 6,365,164	04/02/2002	Schmidt	
	AN	US- 6,063,768	05/16/2000	First	
	AO	US- 6,395,277	05/28/2002	Graham	
	AP	US- 6,265,379	07/24/2001	Donovan	
	AQ	US- 6,358,513	03/19/2002	Voet et al	
	AR	US- 6,328,977	12/11/2001	Donovan	
	AS	US- 6,306,423	10/23/2001	Donovan	
	AT	US- 6,312,708	11/06/2001	Donovan	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	BD	WO94/15629	07/21/94	AS Synapse Biol.		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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**(Use as many sheets as necessary)**

Sheet	2	of	7
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<b>Application Number</b>	10/757,077
<b>Filing Date</b>	January 14, 2004
<b>First Named Inventor</b>	Lance E. Steward
<b>Art Unit</b>	Not Yet Assigned
<b>Examiner Name</b>	Not yet Assigned
<b>Attorney Docket Number</b>	ALLE0014-103 (17355CIP3)

[illegible][illegible]

Date Considered

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 3 of 7

**Complete if Known**

Application Number	10/757,077
Filing Date	January 14, 2004
First Named Inventor	Lance E. Steward
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	ALLE0014-103 (17355CIP3)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BE	ADENIS, et al., J. Fr. Ophthalmol. (1990) 13:259-264.	
	BF	BINZ, et al., J. Biol. Chem. (1990) 265:9153-9158.	
	BG	BLITZER, et al., Ann. Otol. Rhinol Laryngol. (1985) 94:591-594.	
	BH	BRIN, et al., Advances in Neurology, Vol. 50: Dystonia 2 (1988), pp. 599-608.	
	BI	CENCI DI BELLO, et al., Eur. J. Biochem. (1994) 219:161-169.	
	BJ	COHN, et al., Neurology (1987) 37 (3 Supp. 1):123-124.	
	BK	DARSOW, et al., J. Cell Biol. (1998) 142:913-922.	
	BL	ELSTON, et al., Br. J. Ophthalmol. (1985) 69:718-724.	
	BM	FAUCI, et al., "Harrison's Principles of Internal Medicine, 14 <sup>th</sup> ed., (1998) McGraw-Hill.	
	BN	ELSTON, et al., Br. J. Ophthalmol. (1985) 69:891-896.	
	BO	GALLI, et al., Cell (1998) 9:1437-1448.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 4 of 7

**Complete if Known**

Application Number	10/757,077
Filing Date	January 14, 2004
First Named Inventor	Lance E. Steward
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	ALLE0014-103 (17335CIP3)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BP	JANCOVIC, et al., Neurology (1987) 37:616-623.	
	BQ	KADKHODAYAN, et al., Protein Express. Purif. (2000) 19:125-130.	
	BR	KOZAKI, et al., J. Med. Sci. Biol. (1981) 34:61-68.	
	BS	LACY, et al., Nat. Struct. Biol. (1998) 5:898-902.	
	BT	LI, et al., Biochemistry (1994) 33:7014-7020.	
	BU	MAISEY, et al., Eur. J. Biochem. (1988) 177:683-691.	
	BV	MARTINEZ-ARCA, et al., J. Cell Biol. (2000) 149:889-899.	
	BW	MILTON, et al., Biochemistry (1992) 31:8799-8809.	
	BX	MINTON, in Clostridial Neurotoxins: the molecular pathogenesis of tetanus and botulism, Montecucco, ed., Springer Verlag, NY, 1995, pp. 161-194.	
	BY	PEDEN, et al., J. Biol. Chem. (2001) 276:49183-49187.	
	BZ	SWAIN, et al., Peptide Res. (1993) 6:147-154.	

Examiner  
SignatureDate  
Considered

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Sheet 5 of 7

**Complete if Known**

Application Number	10/757,077
Filing Date	January 14, 2004
First Named Inventor	Lance E. Steward
Art Unit	Not Yet Assigned
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Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	ZHOU, et al., Biochemistry (1995) 34:15175-15181.	
	CB	SHIN, et al., J. Biol. Chem. (1991) 266:10658-10665.	
	CC	RASIBORSKA and CHARLTON, Can. J. Physiol. (1999) 77:679-688.	
	CD	ERDAL, et al., Arch. Pharmacol. (1995) 351:67-78.	
	CE	RAGONA, et al., The Larangyscope (1999) 109:1344-1346.	
	CF	NAUMANN, et al., Eur. J. Neurol. (1999) 6:S111-S115.	
	CG	KELLER, et al., FEBS Lett. (1999) 456:137-142.	
	CH	DIETRICH, et al., J. Cell. Biol. (1997) 138:271-281.	
	CI	GEISLER, et al., J. Biol. Chem. (1998) 273:21316-21323.	
	CJ	TAN, et al., J. Biol. Chem. (1998) 273:17351-17360.	
	CK	LIU, et al., Trends Cell Biol. (1999) 9:356-363.	

Examiner Signature		Date Considered	
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 6 of 7

**Complete if Known**

Application Number	10/757,077
Filing Date	January 14, 2004
First Named Inventor	Lance E. Steward
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	ALLE0014-103 (17355CIP3)

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	CL	CAI and SINGH, Biochemistry (2001) 40:4693.	
	CM	TIKKANEN, et al., Traffic (2000) 1:631-640.	
	CN	RAPAPORT, et al., EMBO J. (1998) 17:2148-2155.	
	CO	MIRANDA, et al., JBC Papers in Press (2001) 1-35.	
	CP	COWLES, et al., Cell (1997) 91:109-118.	
	CQ	AOKI, et al., J. Neurol. (2001) 248 (Supp 1):3-10.	
	CR	AOKI, Toxicon. (2001) 12:1815-1820.	
	CS	"Protein Turnover and Autograpij," American Society for Cell Biology.	
	CT	WIEGAND, et al., Nauny Schmiedberg's Arch. Pharmacol. (1976) 292:	
	CU	HABERMAN, Nauny Schmiedberg's Arch. Pharmacol. (1974) 281:	
	CV	THOMPSON, et al., Eur. J. Biochem. (1990) 189:73.	

Examiner  
SignatureDate  
Considered

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Sheet 7 of 7

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Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CW	DI BELLO, et al., Eur. J. Biochem. (1993) 219:161.	
	CX	ARNON, et al., "Botulinum toxin as a biological weapon: medical and public health management," JAMA (2001) 285:1059-1070.	
	CY	ESWARAMOORTHY, et al., "A novel mechanism for Clostridium botulinum neurotoxin inhibition," Biochemistry (2002) 41:9795-9802.	
	CZ	AOKI, et al., "Is the light chain subcellular localization an important factor for Botulinum neurotoxin duration of action?," Naunyn Schmiedeberg's Arch. Pharmacol. (2002) 365 (Suppl 2):R10.	
	DA	FERNANDEZ-SALAS, et al., "Localization of BoNT light chains in neuronal and non-neuronal cell lines, implications for the duration of action of the different serotypes," Naunyn Schmiedeberg's Arch. Pharmacol. (2002) 365 (Suppl 2):R19.	
	DB	STEWART, et al., "BoNT/A light chain and the dileucine motif: potential implications for light chain localization and neurotoxin duration of action," Naunyn Schmiedeberg's Arch. Pharmacol. (2002) 365 (Suppl 2):R44.	

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